genzyme
SURGICAL PRODUCTS

K001434

JUN 12 2000

DEKNATEL PRODUCT GROUP
SEPRA PRODUCT GROUP
SNOWDEN PENCER PRODUCT GROUP
600 Airport Road
Fall River, MA 02720-4740
508-677-6600

EXHIBIT A

510(k) Summary of Substantial Equivalence

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer	Genzyme Surgical Products 600 Airport Road Fall River, MA 02720-4740
Contact Person	Mary E. Gray Phone: (508) 677-6512 Fax: (508) 677-6663 e-mail: mgray@genzyme.com
Date Prepared	April 27, 2000

Device Information

Trade Name:	'cottony' II DACRON, "silky" II POLYDEK® & TEVDEK® II Polyester Nonabsorbable Surgical Suture.
Common Name:	Polyester Nonabsorbable Surgical Sutures.
Classification	Name: Non-Absorbable Poly(ethylene terephthalate) Surgical Sutures

Indications for Use

Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Device Description

Polyester Nonabsorbable Surgical Suture, U.S.P. size 2 available as undyed or D & C Green No. 6 dyed. The suture is sterile, braided and is provided in a variety of lengths, with or without pledgets, attached to needles, using medical grade adhesives, as single suture single needle or double suture single needle.

EXHIBIT A

510(k) Summary of Substantial Equivalence Cont.

Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the currently cleared Polyester Nonabsorbable Surgical Sutures (#K930738).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ISO 10993-1 Biological Evaluation of Medical Devices, U.S.P. Section XXIV - Nonabsorbable Surgical Sutures, and the FDA Guidance Document *"Alternate Suture Labeling Resulting from January 11, 1993 Meeting with HIMA"*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2000

Ms. Mary E. Gray, RAC
Regulatory Affairs Specialist
Genzyme Surgical Products
600 Airport Road
Fall River, Massachusetts 02720-4740

Re: K001434
Trade Name: "cottony" II Dacron, "silky" II Polydek® & Tevdek® II Polyester Nonabsorbable Suture
Regulatory Class: II
Product Code: GAT
Dated: May 4, 2000
Received: May 8, 2000

Dear Ms. Gray:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The "cottony" II Dacron, "silky" II Polydek® & Tevdek® II Polyester Nonabsorbable Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than high molecular weight fibers composed of long chain linear polyester having recurrent aromatic rings as an integral component. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the "cottony" II Dacron, "silky" II Polydek® & Tevdek® II Polyester Nonabsorbable Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, The Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control Provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001434

510(k) Number (if known)

Device Name

'cottony' II DACRON,
"silky" II POLYDEK® & TEVDEK® II
Polyester Nonabsorbable Surgical Suture

Indications for Use

Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001434

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)